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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,647	07/07/2001	Dale R. Lovercheck	ANAL-VIT	6584

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EXAMINER	
HUI, SAN MING R	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/900,647	LOVERCHECK, DALE R.	
	Examiner	Art Unit	
	San-ming Hui	1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): 35 USC 112, second paragraph.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See attachment.*

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None.*

   Claim(s) objected to: *None.*

   Claim(s) rejected: *26-30,33-35,37-46,48,50-54,59-61,64-69,71-74, 76-83,86,87 and 91-94.*

   Claim(s) withdrawn from consideration: *49,55,57,58,62,63,70,85 and 88-90.*

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

ADVISORY ACTION

Continuation of 5):

Applicant's arguments of long felt need have been considered, but are not found persuasive. It states that the claimed subject matter solved a problem that was long standing in the art. However, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04. Examiner also notes that the articles Applicant cited merely related to aspirin and the general health of women, which is not related to the elected compounds herein.

Applicant's arguments averring "nutritional supplement product Law does not apply to drugs" have been considered, but are not found persuasive. Please note that the instant composition comprising ibuprofen and vitamin C. Ibuprofen is a pain reliever, i.e., drug. Therefore, putting the information about dosage of ibuprofen in the package insert is mandated by law, and is obvious to one of ordinary skill in the art.

Applicant's arguments averring "putting nutrition information on a pain reliever label is not obvious, because nutrition is an undisclosed and unintended use of the applied prior art pain reliever" in page 14 of the response filed April 1, 2004 have been considered, but are not found persuasive. Please note that the instant composition comprising ibuprofen and vitamin C. Vitamin C is a nutritional supplement. Therefore,

putting the information about RDA of vitamin C in the package insert is mandated by law, and is obvious to one of ordinary skill in the art.

Applicant's arguments in page 15 and 16 of the response filed April 1, 2004 in regard to "Intended purpose, not function, defines both nutritional supplement products and discomfort reliever products" have been considered, but are not found persuasive. Examiner notes that the instant claims recite "a method of indication for a unit dose of an orally consumable material for relief of discomfort and supplementing nutrition". One of ordinary skill in the art would see vitamin C is a nutritional supplement. And therefore, putting the information about the amount of vitamin C in the package insert is mandated by law, and is obvious to one of ordinary skill in the art.

Applicant's arguments averring superior results have been considered, but are not found persuasive. Please see the discussion in previous advisory action mailed March 24, 2004.

Applicant's arguments averring "Food labeling requirements are not mandatory for drug products" in page 17 and 18 of the response filed April 1, 2004 have been considered, but are not found persuasive. Although food labeling requirements are not mandatory for drug products, the instant composition comprises ibuprofen and vitamin C. Vitamin C is a nutritional supplement. Therefore, putting the information about the amount of vitamin C in the package insert is mandated by law, and is obvious to one of ordinary skill in the art.

Applicant's arguments averring "drug labeling law [21 CFR 201.57] does not mention percent daily value, nutrition or dietary supplements" in pages 19 and 20 in the

response filed April 1, 2004 have been considered, but are not found persuasive. Based on Krause, it is mandatory for nutrition manufacturer to list the recommended daily value of vitamin C of the food product on the package label. In the instant case, the instant composition contains vitamin C and therefore, putting the information about the amount of vitamin C in the package insert is mandated by law, and is obvious to one of ordinary skill in the art.

Throughout the response filed April 1, 2004, Applicant seems to argue that 1) drug products are not governed by nutrition labeling law and/or 2) nutritional products are not governed by the drug labeling law; and therefore, it is unobvious to put information about the instant active ingredients, which contains ibuprofen and vitamin C, on the label or package insert. These arguments are not found persuasive because they do not relate to the grounds of rejection under 35 USC 103(a) set forth in the previous office action. Applicant apparent confuses or mischaracterizes the rejection set forth in the previous office action that 1) putting the information about ibuprofen on the label is motivated by the fact that it is mandated by the nutrition labeling law and 2) putting the information about vitamin C on the label is motivated by the fact that it is mandated by the drug labeling law. This is not the case. As discussed above, 1) putting the information about ibuprofen (note: a drug) on the label is motivated by the fact that it is mandated by the drug labeling law and 2) putting the information about vitamin C (note: a nutritional supplement) on the label is motivated by the fact that it is mandated by the nutrition labeling law. [emphasis added]

Applicant's arguments averring the cited prior art's failure to teach or suggest vitamin C as nutrition supplement and therefore a teaching away of the instant invention have been considered, but are not found persuasive. Firstly, the cited prior art does not expressly exclude the use of vitamin C as nutritional supplement. Secondly, it is well-known in the art that vitamin C as useful as nutritional supplement. Examiner notes that teaching away has to be explicit and positive. In the instant case, there is no specific teaching against the use of vitamin C as nutritional supplement. Therefore, absent evidence to the contrary, it is obvious to one of ordinary skill in the art that vitamin C can be functioned and useful as nutritional supplement.

Applicant's arguments averring the intended use defining both nutritional supplement products and discomfort reliever products and in so doing defines what is required to be printed on the packaging have been considered, but are not found persuasive. As discussed in the previous office action, Applicant constructively argues that the patentability of the instant invention hinges on the "label", indication, or the printed materials. Attention is drawn to *In re Miller* 164 USPQ 46 (CCPA1969) and *In re Gulack* 217 USPQ 401 (CAFC) 1983. In *Miller*, the Court relies on the fact that there is a functional relationship between a measuring cup and the indicia (printed material) on the cup. A cup is not a measuring cup without the indicia since one cannot employ the cup (without indicia) to take accurate measurements. In other words, the content of the printed materials bear no patentable weight unless a functional relationship between the label and the actives is found. In the instant case, a patient can take a medication even without having the written instructions at hand. The ultimate function of the instant

composition relies not on the written instructions, but on the active pharmaceutical ingredient, i.e., ibuprofen and vitamin C, contained therein. The Court in *In re Gulack* also states that "where the printed material is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." Here, the set of instructions is not functionally related to the composition because the composition can function as an active and effective drug even in the absence of the set of instructions (i.e., package insert or indication). Therefore following the reasoning in *Miller* and *Gulack*, we can conclude that the "printed material", i.e., the indication or package insert, does not patentably distinguish the instant claims over the prior art.

Applicant's arguments with regard to "The fact that printed matter by itself is not patentable subject matter because non-satutory, is no reason to ignore it when the claim is directed to a combination" have been considered, but are not found persuasive. Firstly, it is not clear what the legal basis to support such assertion. Secondly, the Court ruled that the printed materials are given patentable weight only when a functional relationship between the label and the actives is found. In the instant case, n such relationship is found. See also the discussion above.

Applicant's arguments in regard to *In re Gulack* have been considered, but are not found persuasive. As discussed before, the printed materials are given patentable weight only when a functional relationship between the label and the actives is found. In the instant case, n such relationship is found. See also the discussion above. Applicant also argues that "the court has cautioned against liberal use of printed mater rejections,

In re Lowry 32 F3d 1579, 32 USPQ 2d 1031 (CAFC, 1994)". The arguments are not found persuasive. In Lowry, data processing systems and data structure are not printed matter because data processing systems are functionally linked and critical to how the data being processed. A functional relationship can be established in Lowry; however, such functional relationship cannot be established in the instant case. The printed matter is not critical to the function of the active. The set of instructions is not functionally related to the composition because the composition can function as an active and effective drug even in the absence of the set of instructions (i.e., package insert or indication).

Applicant's arguments with regard to lack of teachings for combination of references, hindsight reasoning, teaching away of the cited prior art, and superior results have been considered, and are not found persuasive. They have been addressed in the above or in the previous office actions mailed March 24, 2004 and January 28, 2004.

Applicant's arguments with regard to all limitations of a claim must be considered meaningful have been considered, but are not found persuasive. The arguments have been addressed in the final rejection mailed January 28, 2004.

Applicant's arguments with regards to topical treatments of Yeh et al. have been considered, but are not found persuasive. Such arguments were addressed in fprevious rejections mailed January 28, 2004. Yeh et al. clearly teaches the composition be formulated into tablets, pills, capsule, and other oral dosage forms (See Yeh et al., col. 2, lines 13-15).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Patent Examiner
Art Unit 1617